K060766

Non-Confidential Summary of Safety and Effectiveness

21-Feb-06

JUN - 9 2006

Omron Healthcare, Inc.
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Official Contact: Donna Djinovich – Regulatory Affairs Manager

Proprietary or Trade Name: HCG-801 Portable ECG Monitor

Common/Usual Name: Portable, ECG Monitor

Classification Name: Class II

Device: Omron HCG-801 Portable ECG Monitor

Predicate Devices: CG 5000 ECG Mini Monitor Transmitter K992696

Device Description:

The Omron HCG-801 portable ECG Monitor is activated by the user whenever symptoms (palpitations, skipped beats, pounding heart) are experienced. The recorded data serves as reliable evidence and are later shown to physicians or other health care professionals for confirmation of these symptoms. When a user feels that a cardiac event is occurring, the utilization of HCG-801 has the unique feature of recording this real time data that is normally difficult to capture.

HCG-801 portable ECG Monitor is a dry single lead electrode, handheld, portable, self-testing electrocardiograph (ECG) device that records cardiac event data and displays the data in a clear and precise waveform.
HCG-801 portable ECG Monitor has been developed considering ergonomic product designs to provide a clear display and an accurate measurement of waveforms as well as actual usage flow. The device is very simple to use. After turning the device on, the user holds it in their hand insuring that the index finger is placed so that it fits closely over the two finger electrodes. The chest electrode is placed on bare skin about 5 cm (2 inches) below left nipple. The START button is then pressed. Measurement takes about 30 seconds to complete then the unit beeps. No gel usage is necessary and no lead wires are connected.

The recorded data can also be downloaded to Personal Computer via SD memory card that has the capability of storing 300 measurements. This device is not intended for use as a diagnostic tool. This device is also not intended for recording and transmission of user's ECG signal simultaneously. This device is not recommended for users with implanted pacemakers.

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Indications for Use:

The Omron HCG-801 portable ECG Monitor is intended for recording and displaying ECG data by adult patients who are concerned about their heart rhythm. This Omron HCG-801 portable ECG Monitor allows the consumer to record their ECG data into the device memory for display by healthcare professionals during office visits.

Specifically, Omron HCG-801 portable ECG Monitor is intended for adult patients who are concerned about their heart rhythm or have experienced the following symptoms that are suggestive of abnormal heart rhythm:
-Skipped beats
-Pounding heart (palpitations)
-History of arrhythmia

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Environment of Use -- Prescription

Device Attributes:

Features	HCG-801
Indications for use	Self testing of patients intended for recording and displaying real-time ECG data by adult consumers who are concerned about their heart rhythm.
Environment of Use	Prescription use for self testing anywhere and anytime.
Patient Population	Adult
Type of waveform	Real Time ECG Waveform Display
Hear Rate Range	2 to 200 beats/min.
Software driven	Yes
Materials in patient contact	Material is identical to a previously approved Omron HBF-400 Model K043060.
Standard met	IEC 60601-1, IEC 60601-1-2, AAMI EC 38
Measurement Rate	30 Seconds
Components	SD Card, 2 AAA Batteries, storage pouch, instruction manual, quick reference card, warranty card, registration card
Operating conditions	+10 to +40 ℃ 30 to 85%RH (relative humidity)
Storage conditions	-20 to +60 ℃ 10% to 90% RH
Dimensions (mm)	121 mm (W) × 67 mm (H) × 24 mm (D)
Weight (kg) without battery	130 Grams

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Differences Between Other Legally Marketed Predicate Devices

The Omron HCG-801 portable ECG Monitor is viewed as substantially equivalent to predicate device: **CG 5000 ECG MiniMonitor Transmitter.** (K992696)

The portable CG-5000 MiniMonitor Transmitter features real-time display of waveform And ECG recording, output to electrocardiograph and trans-telephonic communication capabilities.

BASIC COMPARISONS BETWEEN HCG 801 and CG-5000 ECG MiniMonitor.

	HCG 801	CG-5000 ECG MiniMonitor
SUBSTANTIAL EQUIVALENCE COMPARISONS		K992696
Intended Use	Same	Same
Prescription/ Over the Counter	Prescription	Prescription
Display of waveform	Displays real-time ECG wave-form	Displays real-time ECG wave-form
Type of Transmission	Non Transmission	Transmission and non-Transmission
Lead placement on body	Chest Placement	Chest Placement
Multiple Event Recording	Yes	Yes
Base-line stabilization	Yes	Yes
Battery Life Indicator	Yes	Yes
Optional Cables	No	Yes
Pacemaker Detection	No	Yes

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In summary, the Omron HCG-801 portable ECG Monitor is substantially equivalent to Card Guard Model CG-5000 ECG MiniMonitor in the following ways:

OMRON HCG-801 is schematically similar to Card Guard Model CG-5000 ECG MiniMonitor.
Both devices are portable, personal, single lead electrode non-transmission type ECG monitors. Card Guard Model CG-5000 MiniMonitor does provide the telephone transmission option which is not an option the Omron HCG-801 ECG offers. Both devices are prescription devices intended for self-testing by patients under doctors' supervision. In both devices, user is required to place device on his/her chest and hold it steadily for at least 30 seconds.
In both devices the user is not required to apply external electrodes to the body although the Card Guard Model CG-5000 ECG MiniMonitor provides electrodes as an option.

Both devices have the capability to record real time heart rhythm waveform and heart beat and store data that can be displayed and downloaded.

The Omron HCG-801 portable ECG Monitor constitutes a safe, accurate, and reliable means for recording of ECG data. When this device is used as intended it is as safe and effective as the predicate device. As shown, Omron HCG-801 device has generally the same technological characteristics and intended use as CG 5000 ECG MiniMonitor but more advantageous and practical in terms of ease of use and reliability.

Validation testing contained in the submission demonstrates that any differences in their technological characteristics do not raise any new questions of safety and effectiveness. When the device is used as it is intended it poses no adverse health effects or safety risks to users.

Performance Testing:
We performed the following bench testing to demonstrate safety and effectiveness and equivalency to the predicate device:

IEC 60601-1 Medical Electrical Equipment Part 1: General Requirements for Safety; Amendment 1, 1991-11, Amendment 2, 1995-03. Version 1995

EMC tests according to IEC 60601-1-2 Medical Electrical Equipment-Part 1-2: General Requirements for Safety-Collateral Standard: Electromagnetic Compatibility-Requirements and Tests. Version 2001.

AAMI EC 38 Ambulatory Electrocardiographs (which includes testing with a known database, e.g., MIT, AHA)

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Conclusion:

Based upon the performance testing and comparison to legally marketed predicate device (for indications for use, technology, and performance) we have demonstrated that the Omron HCG-801 Portable ECG Monitor is substantially equivalent in safety and effectiveness to the predicate device.

There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 9 2006

Omron Healthcare, Inc.
c/o Ms. Silvia Ankova
Project Engineer
Underwriters Laboratories, Inc.
333 Pfingsten Rd
Northbrook, IL 60062

Re: K060766
Trade Name: HCG-801
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: II (two)
Product Code: DPS
Dated: May 22, 2006
Received: May 25, 2006

Dear Ms. Ankova:

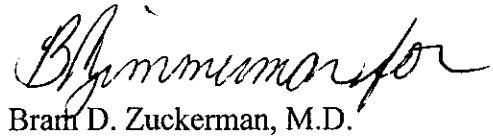
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K060766 (To be assigned)

Device Name: Omron HCG-801 Portable ECG Monitor

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Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K060766